BOYCE & ISLEY, PLLC

ATTORNEYS AT LAW

LAWYERS WEEKLY BUILDING, SUITE 500
POST OFFICE BOX 1990
RALEIGH, NORTH CAROLINA 27602-1990

G. Eugene Boyce
R. Daniel Boyce
Philip R. Isley
Laura Boyce Isley

107 Fayetteville Street, Suite 500
Raleigh, North Carolina 27601

Telephone: (919)833-7373
Facsimile: (919)833-7536

June 23, 2009

AMENDED JUNE 23, 2009

Via electronic mail and U.S. Mail

John A. Wasco
Senior U.S. Probation Officer
Eastern District of North Carolina
Terry Sanford Federal Building
310 New Bern Avenue, Room 610
Raleigh, North Carolina 27601-1461

Re: ***United States v. Philip Joe Guyett, Jr.***
EDNC No. 5:09-CR-40-BR-1

Dear Mr. Wasco,

Set forth below are the timely objections of Philip Joe Guyett, Jr. to the draft presentence report sent May 22, 2009.

PART A: THE OFFENSE

The Offense Conduct

Page 3, Paragraph 5:

There are multiple steps for the processing of tissue: (1) recovery; (2) screening and processing; and (3) storage and distribution. All of the processors with whom Philip Guyett had contracts were registered with the FDA for recovery, screening, processing, storage, and distribution. Furthermore, they all were accredited by the American Association of Tissue Banks (AATB) which has national standards regarding tissue banking. Philip Guyett was not registered to screen donors. His role was limited to recovery of the tissue. The screening, processing, storage and distribution followed. Mr. Guyett agrees there are two steps of donor testing and donor screening. The draft PSR should note that: (1) Philip Guyett was not registered with the FDA for screening; and

EXHIBIT 1

(2) It takes a medical director (MD) in good standing to deem the donor suitable for transplant after reviewing relevant medical records (as mentioned in #5, including hospital records, coroner's office records, death certificates and sometimes autopsy reports). (See **Exhibit A**, FDA Registration of Donor Referral Services & **Exhibit B**, AATB Standards).

Mr. Guyett conducted preliminary screening for recovery purposes only. He had the right to reject a donor. It would not be in his interest to invest $500-$1500 in recovery supplies only to have the donor rejected down the line. Every phase of the donation process had the risk of rejection, be it the donor or a specific graft. Mr. Guyett's screening alone was preliminary and should not have been used in the ultimate determination of release of tissue grafts. Recovered tissue cannot move past the quarantine point until it has been screened and cleared by the medical director of the screening establishment. Being registered as a screening establishment by the FDA shows that the establishment has the trained personnel for that function. Even if he had all of the medical records in front of him, along with a certified death certificate, Mr. Guyett still could not deem a donor's tissue eligible for transplant. He could only go as far as recovery. Only a medical director can conduct the final donor eligibility screening for tissue release, and all relevant medical records are needed at that time (not just Mr. Guyett's preliminary information).

Mr. Guyett has acknowledged his falsifications of funeral home death records. But, since the FDA had to acquire certified death certificates on the 100 donors that were reviewed, the PSR therefore is suggesting that Mr. Guyett and the processors failed to properly obtain, review and screen the donors for transplant suitability per AATB Standards. (See **Exhibit C** regarding the requirement of third party records). However per the AATB, the medical and social history information was a preliminary review for recovery purposes only. (See **Exhibit D**, AATB Standards, "Steps in the Tissue Retrieval Process.") This information may be started before recovery, but should be completed by trained personnel after the recovery process and after the processor has quarantined the recovered tissue. Again, Mr. Guyett was never trained, registered or certified for the subsequent step involving screening, including medical records review, and he did not represent himself to be trained or certified for such work. The fact that the standards do not state that the medical social history form be performed before or after recovery only shows that it is one of many relevant medical records that are needed for the screening process. Per the AATB standards, tissue recovery has to be performed within 12-24 hours after death. Many times the consent is not given until the 20th hour. DRS did not perform hospital recoveries so DRS was never able to obtain official medical records for review before the recovery. If DRS did, Mr. Guyett was obligated to forward the information to the processor. Since the charts have no such records(per FDA Audits), under the regulations the results would be that the processors failed to properly obtain the relevant records for determining donor suitability for transplant. However this is inconsistent with the findings by the FDA. Given the fact that the tissue recovery processing and distribution had in place significant screening and quality assurance procedures, "no adverse reactions associated with these tissues have yet been reported, and subsequent processing should reduce the potential risks of infectious disease

transmission…In addition, these tissues subsequently underwent processing steps at other sites that are designed to reduce the risk of disease transmission". (See **Exhibit E,** FDA Public Health Notification: Donor Referral Services).

In sum, Mr. Guyett was responsible for submitting two documents: the medical social history questionnaire and the physical assessment. Those two documents alone are not enough to screen donor tissue for determining eligibility for transplant, but instead are only used to screen a donor for recovery. Mr. Guyett only had access to the recovered tissue for 4-48 hours. He did not have the types of freezers to hold donor tissue past that time period. The tissue is placed in quarantine per AATB and FDA so that adequate records can be obtained and reviewed. The subsequent testing and processing should have resulted in checks and balances to prevent any inappropriate tissue from being distributed. Based on the FDA's findings the checks and balances apparently worked.

Page 4, Paragraph 5 Continued:

Donors can be rejected for other medical conditions. The draft PSR fails to mention that the information comes after recovery and is reviewed during the quarantine period and was earlier labeled "Tissue To Be Placed In Quarantine – Not Deemed Suitable For Transplantation At This Time." (i.e. after Mr. Guyett has transferred the recovered tissue) (See **Exhibit F**, FDA Standards and AATB Standards)

Page 4, Paragraph 7:

Mr. Guyett's company was only registered as a tissue recovery service. (See **Exhibit A,** Copy of FDA Registration for Donor Referral Services). Mr. Guyett closed Donor Referral Services in 2005. He gave notice to the FDA, filed an inactive form and ended business in December 2005. (See **Exhibit G**). Inspection by the FDA was performed 6 months after the business was closed which was confirmed by the Atlanta Office of the FDA.

Page 4, Paragraph 8:

After closing the doors to the business, original donor charts were sent by Mr. Guyett to the processors per the advice of the Washington, DC Office of the FDA in October 2005. The FDA obtained certified death certificates for their investigation. The donors could not have been screened without them, proving that Mr. Guyett did not supply certified death certificates to the processors. If the processors' medical director did not have the relevant medical records (including certified death certificates rather than the records provided by a funeral home (some of which Mr. Guyett acknowledged he falsified), then they violated the screening process set forth by the FDA & AATB. The processors would have been in violation of the FDA & AATB Standards regarding this important step. As mentioned above, Mr. Guyett only conducted preliminary screening and was not registered to screen donors since he was not a medical doctor.

Page 4, Paragraph 9:

Mr. Guyett objects to donor records from Las Vegas, Nevada being included as "relevant conduct." The "Explanation of the Presentence Report" specifically calls for two distinct sections: "The Offense Conduct" and "Offense Behavior Not Part of Relevant Conduct." The draft PSR lumps together offense conduct (in the Eastern District of North Carolina during the time frame set forth in the Criminal Information) as well as "Offense Behavior Not Part of Relevant Conduct" (in Las Vegas, Nevada, outside the time and scope set forth in the Criminal Information).

Although the report suggests that 37% of the donors may have shown problems, many of them were found to have conditions such as cancer and dementia. These two conditions do not rule out donation per AATB Standards. (See **Exhibit H**). The medical director must review their records. Mr. Guyett was not involved during that part of the process. After you take out the falsified records related to eight donors, a substantial percentage of the remaining 33 or 34 donors could have been cleared for transplant.

Also, Mr. Guyett has acknowledged he falsified funeral home death records. Mr. Guyett did not falsify death certificates. Death certificates have the registrar's name and the county stamp on them. Furthermore, they are watermarked for security. Mr. Guyett neither obtained nor supplied death certificates to the processors, he provided falsified funeral home records.

Mr. Guyett only received payment for the recovery once the processors fully screened the donors. Once paid, Mr. Guyett assumed that the processors were following FDA & AATB Standards in reviewing relevant medical records. Mr. Guyett was first made aware during the FDA's investigation that approximately 100 donors were cleared by the processors' medical director without any medical records of any kind. He had no control over the tissue at that stage.

Mr. Guyett did not have a contractual agreement with the donors. Mr. Guyett's only contractual agreements were between DRS and the processors (Lost Mountain Tissue Bank ("LMTB"), Alamo Tissue Services ("ATS") and U.S. Tissue & Cell ("USTC")) and the distributor (Tissue Net Distribution Services ("TN")).

Page 4, Paragraph 10:

Mr. Guyett has acknowledged he falsified records to get rid of tissue because he had to close down his business due to economic failure of the business. He did not use the phrase "this was done for monetary gain."

Page 5, Paragraph 11:

Mr. Guyett opened the First Citizens Bank account in October of 2004 and it was closed some time in 2006 with a $1,300.00 negative balance. (See **Exhibit I** and **Exhibit J**). During the time frame in the scope of the relevant conduct (March 2005 to

December 2005) Mr. Guyett did not conduct $391,392 worth of fraudulent business. Deposits made to the First Citizens account prior to March 2005 include money earned during a period of time outside the scope of the relevant conduct and therefore should be excluded from the total amount of loss. Furthermore, portions of the money deposited in to the company's account were Mr. Guyett's personal contributions totaling $32,377.44; and other portions of the money were acquired by Mr. Guyett for conducting research on behalf of various companies totaling $56,865.25. (See **Exhibit K** attached). These deposits are unrelated to any of the recoveries conducted by Mr. Guyett during the relevant conduct period and therefore should be excluded from the total loss amount.

The only money Mr. Guyett made and deposited relating to the falsification of donor records while in the Eastern District of North Carolina and during the relevant conduct period was approximately ***$28,000*** (approximately 8 recoveries from 8 donors during this time frame involving the falsification of donor records and therefore should be the only money attributable as monetary amount of loss).

Page 5, Paragraph 13:

The selling of tissue is illegal per the Uniformed Anatomical Gift Act. Mr. Guyett was not paid for tissue; he was paid for recovery services. The victims were the processors (four total), not the recipients of the tissue grafts (per the definition of VICTIM regarding actual loss and pecuniary harm). There are only three victims associated with the above amount totaling approximately ***$28,000.*** Mr. Guyett never had patient contact and because of the subsequent steps, any problems with the tissues should have been identified. By the time the tissue was implanted, it had gone through many other hands and channels. The fact is the recovery establishment (DRS), the processors (LMTB, ATS and USTC) and the distributor (TN) all work together to produce a product. A recovery establishment's role alone cannot produce the finished graft. DRS recoveries were of whole bone & tendon. These tissues are not life saving tissue but are regarded as life enhancing. It is not like a heart transplant. The tissue goes through many hands and screeners because it is not life saving. The processors have the time to screen the donor. The tissue can be quarantined for up to 10 years if needed in order to undergo proper screening and testing. The recovery agent has no control over how the tissue will be processed and what types of grafts will be made. The recovery agent also has no control over what hospital gets the graft and who the recipient will be. It may take 6 months to 10 years before the graft is even used. The money paid came from the processors only and Mr. Guyett was not compensated by a recipient or a hospital. His fee was only for recovery of raw material.

PART B. DEFENDANT'S CRIMINAL HISTORY

Criminal Convictions

Page 5, Paragraph 14:

To Mr. Guyett's knowledge, he was not arrested on suspicion of murder. He only was questioned about the cadaver from Western University. Further, Mr. Guyett was under the impression the case was expunged. (See **Exhibit L**).

PART D: GUIDELINES COMPUTATIONS

Offense Level Computations

Page 9 , Paragraph 33

Given the gain to the defendant of the fraudulent activity was $28,000 as set forth above, the twelve level increase is erroneous. The specific offense characteristic for loss in excess of $10,000 but less than $30,000 calls for a four level increase.

Page 9, Paragraph 34:

As set forth above, there were three company victims (Tissue Net, U.S. Tissue and Cell and Alamo) that received false paperwork associated with eight donors. Therefore there are three company victims not 127 victims. Therefore, a four level increase is not warranted.

Page 9, Paragraph 36:

Given the fact that the tissue recovery processing and distribution had in place significant screening and quality assurance procedures, "no adverse reactions associated with these tissues have yet been reported, and subsequent processing should reduce the potential risks of infectious disease transmission...In addition, these tissues subsequently underwent processing steps at other sites that are designed to reduce the risk of disease transmission". (See **Exhibit E,** FDA Public Health Notification: Donor Referral Services).

Page 9, Paragraph 36:

No victim related adjustment for vulnerable victims is warranted under *United States v. Anderson,* 349 F.3d 568 (8th Cir. 2003) or alternatively, under U.S.S.G. § 2B1.1(b), Commentary, Application Note 4, Application of Subsection (b)(2)(D).

Page 9, Paragraph 42:

Based on the above changes, the total offense level should be changed to 11 for a Guideline Range of 8 to 14 months.

PART F: FACTORS THAT MAY WARRANT DEPARTURE OR VARIANCE

We object to speculative nature of the statement that numerous victims received human tissue from donors which was unfit for use as donor material thereby subjecting the recipients to possible infection and that as a result, "the extreme psychological damage to these victims cannot be captured under the Guidelines and therefore the court should consider an upward departure". This is purely speculative and inflammatory and without a factual basis that has been provided in the draft PSR or in discovery provided by the Government.

If the Court accepts the Probation Officer's calculations and rejects the above objections, Mr. Guyett respectfully asserts that a downward variance is appropriate because the twelve level increase based on calculated amount of loss, total number of victims and vulnerable victims does not accurately portray the nature and circumstances of the offense under 18 U.S.C. § 3553(a)(1).

Given the complex nature of the case and the objections set forth above, I believe a conference call with the Government and Defense might help.

Thank you for your consideration of these matters.

Sincerely,

BOYCE & ISLEY, PLLC

R. Daniel Boyce

RDB/jl
Enclosures